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Public Consultation on the revision of EU rules on food contact materials (FCMs)

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Introduction

Food contact materials ('FCMs') include all articles that come into contact with food during its production, processing, storage, transport, preparation and serving, before its eventual consumption. Examples include food packaging, kitchenware and tableware like cups, bowls and cutlery and appliances such as food blenders or coffee machines. It also includes items used in professional food manufacturing, preparation, storage and distribution like conveyor belts and tanks.

No material is completely inert and chemical substances, such as those used in the production of the food contact material may be present in the final article and may transfer to food, potentially resulting in exposure of people consuming that food. Current EU rules are in place to protect consumers and which aim to ensure an effective functioning of the EU market. More information can be found on our website.

The Commission's findings of a recent evaluation of the current EU rules on food contact materials was published in June 2022, which identifies gaps and areas for improvement. This survey seeks your views on a revision of the current EU rules in order to address these gaps and to improve the current legislation.

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FCM stakeholders

The following questions are for stakeholders with some knowledge of food contact materials (FCMs) and the relevant EU legislation. They cover the scope and main elements of the FCM Regulation that the Commission is seeking to revise, in response to the problems identified during the evaluation and commitments given in its various strategies. These concern **placing greater emphasis of the rules onto the final FCM article, prioritisation of substances** including the **most hazardous**, **supporting safe and more sustainable FCMs** and **improving supply chain information, compliance and enforcement**.

Scope of FCM legislation

Q1. To what extent do you agree that the following should be considered a food contact material or article and subject to safety rules:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
* Paper napkins	◉	○	○	○	○	○
* Kitchen paper towels	◉	○	○	○	○	○
* Table cloths	○	◉	○	○	○	○

* Table mats	○	◉	○	○	○	○
* Baby or child's bib	◉	○	○	○	○	○
* Kitchen work surfaces	◉	○	○	○	○	○
* Toys with a similar shape and form as real kitchenware	○	◉	○	○	○	○
* Interior of refrigerators	◉	○	○	○	○	○
* Dining table surfaces	○	○	◉	○	○	○
* Table or desk surfaces not specifically intended for eating	○	○	○	◉	○	○
* Kitchen tiles, splashboards, and other vertically mounted kitchen surfaces	○	○	○	◉	○	○
* Ovens and furnaces, excluding baking trays	○	○	○	◉	○	○
* Shopping bags /boxes available at food retailers	◉	○	○	○	○	○
* Plastic storage containers not marked as suitable for food contact (unlabelled)	○	○	◉	○	○	○

* Inkjet printers if used in combination with edible ink	◉	○	○	○	○	○
* Lubricants used with FCM machinery	◉	○	○	○	○	○
* Coolants used in food industry	◉	○	○	○	○	○
* Fishing equipment (e.g. nets)	◉	○	○	○	○	○
* Serving trays	◉	○	○	○	○	○
* Wooden chips or planks to smoke food	◉	○	○	○	○	○
* Feeding tubes for medical purposes	○	○	○	◉	○	○

If necessary please add examples or elaborate your responses.

All materials that may be in contact with food should be considered as FCMs.
- Toys should be rather covered under the Toys Safety Directive
- Lubricants for FCM machinery should undergo chemical tests to assure that they are innocuous for food (avoiding release of unwanted substances). Ideally that should be valid not only lubricants but every product used for maintenance.
- Feeding tubes should be covered under the Medical Devices Regulation.

Q2. To what extent do you agree that FCM legislation should address the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
* *Allergens* that may be present in FCMs (e.g. wheat straws)	◉	○	○	○	○	○

* *Physical safety* of food contact materials (e.g. choking hazards, sharp edges)	○	○	◉	○	○	○
* *Hygiene and risks from bacteria and other microorganisms* from the handling of FCM including reuse (e.g. in supermarkets or catering establishments)	◉	○	○	○	○	○
* *Environmental* concerns	○	◉	○	○	○	○

Safety and Risk Management

The FCM roadmap foresees a 'tiered' approach to prioritising substances in FCMs including a 'generic risk approach' (GRA) for the most harmful substances, in line with the Chemicals Strategy for Sustainability (CSS), where decision-making is based primarily on generic risk considerations for certain hazardous properties of the substances. Depending on these properties, some substances would be prohibited, with the possibility for limited exceptions where their use is considered essential. Other substances may be subject to a more specific risk assessment at EU level, taking into consideration exposure from FCMs, whereas others would need to be risk assessed and managed primarily by the business operator.

Q3. On what basis should the following FCM substances be risk-managed:

Substances that are:	Priority 1: Generic approach to risk management (GRA)	Priority 2: Specific risk assessment (SRA)	Priority 3: Industry self-assessment	They are not relevant for FCMs	No opinion
* Genotoxic	◉	○	○	○	○
* *Known* or *presumed* to be carcinogenic, mutagenic or reprotoxic (CMR 1A and B)	◉	○	○	○	○
* *Suspected* to be carcinogenic, mutagenic or reprotoxic (CMR 2)	◉	○	○	○	○
* *Known* or *presumed* to be disruptive to the endocrine system (known or presumed 'ED')	◉	○	○	○	○
* *Suspected* to be disruptive to the endocrine system (suspected 'ED')	◉	○	○	○	○
* Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB)	◉	○	○	○	○
* Immunotoxic (adverse effects on the immune system)	◉	○	○	○	○

* Neurotoxic (adverse effects on the neurological system)	◉	○	○	○	○
* Toxic to a specific organ (single target organ toxicity or 'STOT')	◉	○	○	○	○
* Skin sensitizers (able to cause an allergic response following skin contact)	◉	○	○	○	○
* In nano form	◉	○	○	○	○
Other types of substances or hazards (please specify below)	○	○	○	○	◉

Q4 (a). Regulatory intervention can be made at different stages in the supply chain and employ different tools to achieve its aim. For the different priority groups, indicate at what point you consider intervention most appropriate:

	Priority 1 substances	Priority 2 substances	Priority 3 substances	No opinion/ answer
Prohibition or restriction on the ***use of the substance(s) to manufacture FCM***, even if they are not present in the final FCM article (e.g. substance X cannot be used to manufacture FCM)	☑	☐	☐	☐
Prohibition or restriction on substance(s) that may be ***present in the final FCM article***, even if they can be controlled or migration is safe (e.g. substance X cannot be present in FCM)	☑	☐	☐	☐
Prohibition or restriction on substance(s) that ***migrate from the final FCM article into food*** (e.g. no migration of substance X allowed or an applicable SML)	☐	☑	☐	☐

Q4 (b). To what extent do you agree that the following tools are appropriate for the risk management of FCM substances:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* Overall migration limit	◉	○	○	○	○	○
* Purity criteria for substance(s)	◉	○	○	○	○	○

* Specific conditions of use for substance(s)	◉	○	○	○	○	○
* Requirement to identify substances and other information requirements	◉	○	○	○	○	○
* Traceability requirements	◉	○	○	○	○	○
* Labelling requirements for the end user of FCMs	◉	○	○	○	○	○
* Testing requirements and other methods for measuring single substances and groups of similar substances	◉	○	○	○	○	○
* Testing requirements for all potentially migrating substances (multi-analyte methods)	◉	○	○	○	○	○
* Mandatory registration of businesses	◉	○	○	○	○	○

Sustainability and Future Developments

Sustainable development is a priority objective for the EU's policies and features in the Farm to Fork Strategy. The following questions concern sustainability of FCMs.

Q5. To what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* Prohibiting the most hazardous substances in the revised legislation is sufficient to address sustainability as it will contribute to the core sustainable development goal (SDG) of 'good health and well-being'	○	○	◉	○	○	○
* FCM legislation should prioritise and incentivise sustainable FCMs to support the functioning of the EU market (e.g. including harmonised safety rules on bio-based materials, reuse and recycling)	○	○	◉	○	○	○

* FCM legislation should require that information relevant to sustainability is made available, e.g. energy and other resources used in production and recycling levels	○	○	◉	○	○	○
* FCM legislation should include requirements on sustainability of FCMs, as well as safety	○	○	◉	○	○	○
* Environmental legislation (Packaging and Packaging Waste, Eco-design, Sustainable Products Initiative) and the Framework for the Sustainability of Food Systems should achieve sustainable use of FCMs, not the FCM legislation	○	◉	○	○	○	○

* **Q6**. In your view, which aspects of sustainability of FCMs should be assessed?

- ☐ Sustainability of product only (sustainably sourced and produced)
- ☐ Lifecycle-based assessment (LCA)
- ☐ Broader societal framework

- [x] Impact on environment only
- [ ] Socio, economic and environmental impacts (three pillars of sustainability)

Q7 (a). How do you see the market for the following materials develop in the next 10 years?

	Increase significantly	Increase to some extent	Stay the same	Decrease to some extent	Decrease significantly	No opinion
* Plastics or other polymers originating from non-fossil fuel sources (e.g. bioplastics)	○	○	○	○	○	◉
* Materials derived from natural or plant-based sources not including paper and board (e.g. wood, bamboo, cotton [textiles])	○	○	○	○	○	◉
* Materials that are biodegradable or compostable	○	○	○	○	○	◉
* Paper and board from primary materials	○	○	○	○	○	◉
* Paper and board from secondary (recycled) materials	○	○	○	○	○	◉
* Plastic from primary materials	○	○	○	○	○	◉
* Plastic from secondary (recycled) materials	○	○	○	○	○	◉
* Active and intelligent FCM	○	○	○	○	○	◉

Q7 (b). Are there any other types of materials or other new or emerging technologies that you consider should be regulated at EU level? Please motivate your answer:

All materials in annex I of the FCMs regulation should be regulated at EU level (not all of them are listed above).

Q8. In your views, what are the main elements that support innovation of FCMs?

Legal certainty, health and risk assessment

Information along the Supply Chain

Objectives D and E of the roadmap seek to pursue the objectives of improving quality and accessibility of FCM production chain information and supporting this with a system that better ensures compliance and enforcement.

Q9. Concerning demonstration of compliance in the FCM production chain, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* The current declaration of compliance (DoC) (e.g. for plastic FCM) and requirements for information passed in the supply chain are satisfactory	○	○	○	○	◉	○
* A DoC should be mandatory for all FCMs	◉	○	○	○	○	○
* The DoC should be based on a fixed format with obligatory fields	◉	○	○	○	○	○

* An approval step of the final FCM article will improve compliance and safety along the supply chain	○	◉	○	○	○	○
* An approval step of the final FCM article will improve marketing and commercial benefits for businesses	○	○	○	○	○	◉
* Full information on the composition of products shall at all times be easily available to competent authorities throughout the supply chain	◉	○	○	○	○	○
* The supply chain should provide manufactures of final food contact materials with complete information on substances potentially migrating above 10 ppb, whether those are intentionally used or not	◉	○	○	○	○	○

* Compliance information and usage indications can be made available at a batch level for intermediate FCMs	○	○	○	○	○	◉
* Compliance information and usage indications should be made available on individual final articles	◉	○	○	○	○	○
* The permitted use shall be clearly indicated but disclaimers disallowed	○	○	○	○	○	◉

Q10 (a). To what extent do you agree that the following *information* should be required to pass from one business to the next in the production chain, to determine the eventual compliance of the final FCM article:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* Identity of substance(s) used to manufacture FCM	◉	○	○	○	○	○
* Identity of substance(s) used in the processing or conversion of FCM	◉	○	○	○	○	○

* Identity of substance(s) generated adventitiously in the production process (e.g. degradation or reaction products)	◉	○	○	○	○	○
* Identification of hazardous properties and/ or other toxicological information of the identified substances	◉	○	○	○	○	○
* A statement that substances of a high concern (genotoxic, CMRs, EDs) are not present in the product	◉	○	○	○	○	○
* Physical and chemical properties of the identified substances	◉	○	○	○	○	○
* Stability and reactivity of the identified substances	◉	○	○	○	○	○
* Expected migration	◉	○	○	○	○	○

* Exposure data to the identified substances including from other sources besides FCM	○	◉	○	○	○	○
* Restrictions or limitations of the material(s) as regards the food (s) with which it is intended to be brought into contact	◉	○	○	○	○	○
* Restrictions or limitations of the material(s) as regards the time and temperature of treatment and storage in contact with the food	◉	○	○	○	○	○
* Analytical testing to demonstrate the level of substances in the material	◉	○	○	○	○	○
* Analytical testing to demonstrate the level of substances that may migrate into food	◉	○	○	○	○	○

Q10 (b). What other information should be required to pass from one business to the next in the production chain? In particular, what toxicological information should be provided for tier 3 substances?

Q11. Concerning a *system* for transfer of information in the supply chain, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* A DoC and documentation supporting compliance (supporting documentation) should be contained and transferred within a digital or electronic system as opposed to a paper-based system	○	◉	○	○	○	○
* There is already a digital information exchange system such as radiofrequency identification (RFID) or machine readable information (QR) in place in my FCM production	○	○	○	○	○	◉

chain (or will be in the near future) that can be used to pass safety-related information related to FCM						
* Each individual FCM article should have a QR code or equivalent to give information to users of FCMs, including food businesses and consumers and to control authorities for enforcement purposes	○	○	◉	○	○	○
* The system must prevent disclosure of commercially sensitive information in the supply chain, e.g. by using notified bodies/ third parties	○	◉	○	○	○	○
* A centralised digital system should be established for exchange of compliance information	◉	○	○	○	○	○
*						

A decentralised digital system should be established for exchange of compliance information	○	○	○	◉	○	○

Q12. Concerning the roles and responsibilities of different actors, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/ answer
* FCM legislation should clearly identify to which actors (manufacturers of starting substances, convertors, final FCM article producers) specific rules or information requirements apply	◉	○	○	○	○	○
* Notified Bodies should be used for the verification of compliance and would help businesses to ensure safety	○	◉	○	○	○	○
* Notified Bodies would help businesses						

reduce costs of placing their products on the market in the long term, particularly for SMEs	○	○	○	○	○	◉
* Member States competent authorities should carry out regular physical and documentary checks on FCMs	◉	○	○	○	○	○
* Member States competent authorities should be supported by the use of delegated bodies as provided by Regulation (EU) 2017/625 for official controls	◉	○	○	○	○	○

Q13. Please upload any additional documents (e.g. position papers) to support your contribution to the consultation.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

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